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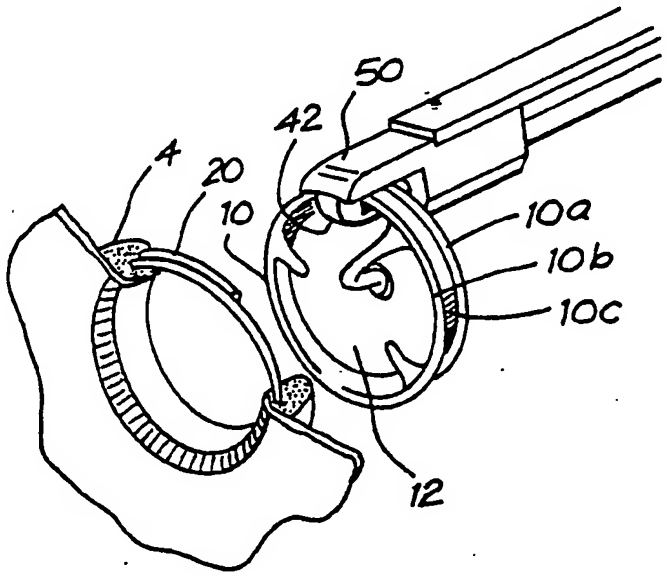
(54) Title: PROSTHETIC HEART VALVE AND INSTRUMENT FOR INSERTING AND/OR REMOVING SAME



(57) Abstract

A prosthetic heart valve (2) comprising a mounting ring (4) of suturable material for suturing into an annulus (6) in the heart, a valve ring (10) carried by said mounting ring and a moveable valve member (12) carried by said valve ring. The mounting ring (4) includes a clamping member (20) clamping said valve ring thereto, said clamping member being operable to release said valve ring and its valve member so as to allow replacement thereof while leaving the mounting ring (4) sutured in the heart. The removable and remplacement of the valve ring (10) is affected by an instrument (30) specifically adapted for use with the prosthetic heart valve. The instrument (30) includes a rod (40) with a first jaw (42) and a slide (48) with a second ja

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PROSTHETIC HEART VALVE AND INSTRUMENT FOR INSERTING AND/OR REMOVING SAME

The present invention relates to prosthetic heart valves used for replacing defective heart valves in a human body, and also to an instrument for use in applying and/or removing the prosthetic heart valve.

The replacement of a defective aortic, mitral, or tricuspid valve by a prosthetic heart valve is now a common surgical operation. The prosthetic heart valve frequently used today includes a mounting ring of suturable material, usually fabric, for mounting the valve in the heart annulus prepared upon removing the defective valve. The mounting ring carries a valve ring and a valve member movable within the valve ring, which valve member controls the blood flow. In one type of prosthetic heart valve commonly used today, the valve ring is a titanium cage, and the valve member is a disc pivotably mounted within the titanium cage.

Prosthetic heart valves frequently require replacement because of clot formation, calcification, or other interference with the movement of the valve member. Statistically, the valve replacement rate is approximately 2.5% per year. Thus, over a ten year period, there is approximately a 25% chance that a prosthetic heart valve in any one individual will have to be replaced. The replacement of a prosthetic heart valve is also frequently required in a growing child, in order to accomodate the increase in size in the child's heart.

Today, whenever a prosthetic valve has to be replaced, the conventional procedure is to completely remove the defective valve by opening its sutures and then resuturing another prosthetic valve in its place.

A substantial part of the time and effort involved in replacing a defective prosthetic heart valve in this manner is in the resuturing of the new prosthetic valve in the place of the defective one. The time period of the operation, and particularly the time period during which the patient's normal blood circulation is blocked for purposes of replacing the defective valve, directly bear not only on the chances of recovery, but also on the period required for recovery. The present procedure, which is very time-consuming, therefore subjects the patient to considerable additional risk and trauma; it also subjects the surgical staff to considerable additional strain and effort.

An object of the present invention is to provide a prosthetic heart valve which can be used for replacing a defective heart valve so as to avoid the above disadvantages in the present technique.

Another object of the present invention is to provide an instrument particularly useful for removing and/or replacing the novel prosthetic heart valve.

According to one broad aspect of the present invention, there is provided a prosthetic heart valve comprising a mounting ring of suturable material for mounting the valve in an annulus in the heart by the use of sutures, a valve ring carried by said mounting ring, and a movable valve member carried by said valve ring; characterized in that said mounting ring includes a clamping member clamping said valve ring thereto, which clamping member is openable to release said valve ring and to permit replacement of the valve ring and its valve member another valve ring and valve member while leaving the mounting ring and its sutures in place in said annulus.

In the preferred embodiment of the invention described below, the clamping member is in the form of a ring having a diameter which is expansible in order to accomodate valve rings of different diameters. More particularly, the clamping member is a coiled spring of annular shape.

It will be thus seen that once such a prosthetic heart valve is sutured in the heart annulus to replace a natural, defective valve, any subsequent replacement of the prosthetic heart valve, e.g., because of clot formation or calcification, does not require the complete removal of the prosthetic valve, but only the removal of the valve ring (and valve member carried thereby) from the mounting ring; the mounting ring and its sutures remain in place in the annulus. The fact that there is no need to remove the sutures of the mounting ring and to resuture a new prosthetic valve in its place effects a very substantial savings in the time required for the surgical operation. As a result there is a substantial decrease in the risk and trauma to which the patient is subjected. Use of the novel prosthetic heart valve is particularly advantageous when replacing a natural valve in a growing child, since the clamping member, being in the form of a ring having a diameter which is expansible, is able to accomodate valve rings of larger diameters as may be required by the increase in the heart size of the growing child. A further advantage in the invention is that the new prosthetic heart valve may be rotated by the surgeon after its implantation, if necessary.

According to a further aspect of the present invention, there is provided an instrument for use in removing a valve member and its valve ring from a clamping ring included within a mounting ring sutured in an annulus in the heart, and/or in inserting

another valve member and valve ring in its place, comprising: a first handle; a second handle pivotably mounted to the first handle and grippable therewith by the user's hand so as to be movable towards and away from the first handle by a hand-squeezing pressure; a fixed jaw fixed at one end to said first handle and having an abutment at its opposite end; and a movable jaw coupled to said second handle by a coupling effective to cause said movable jaw to move towards and away from said abutment along a rectilinear path parallel to the axis of said fixed jaw when the second handle is pivoted towards and away from said first handle.

Such an instrument enables the surgeon to effect the removal of the valve ring and its valve member, and their replacement by another valve ring and valve member should this be required, in a relatively short period of time and with a very substantial decrease in the trauma to which the patient is subjected.

Further features and advantages of the invention will be apparent from the description below.

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

Fig. 1 illustrates one form of prosthetic heart valve constructed in accordance with the present invention;

Fig. 2 illustrates the heart valve of Fig. 1 with parts removed to show internal structure;

Fig. 3 illustrates an instrument which may be used for removing and/or replacing a defective prosthetic heart valve;

Figs. 4a and 4b illustrate steps in the removal of a defective prosthetic heart valve by the use of the instrument illustrated in Fig. 3;

Figs. 5a and 5b illustrate a modification in the instrument of Fig. 3, and its use in the attachment of a new prosthetic heart valve to replace a defective one; and

Fig. 6 illustrates another instrument that may be used in the attachment of a new prosthetic valve to replace a defective one.

The prosthetic heart valve illustrated in Figs. 1 and 2, therein generally designated 2, comprises a mounting ring 4 of fabric or other suturable material for mounting the valve in an annulus 6 in the heart by the use of sutures 8. The prosthetic heart valve further includes a valve ring 10 and a valve member in the form of a disc 12 pivotably mounted by pins 14, 16 to valve ring 10.

Such types of prosthetic heart valves are known, and therefore further details of its construction and operation are not set forth herein.

As brought out earlier, in the conventional prosthetic heart valve, mounting ring 4, valve ring 10, and pivotable valve disc 12 are all formed as a unitary device which is fixed as a unit by sutures 8 when the prosthetic heart valve is used to replace to a defective valve, and is removed as a unit by severing sutures 8 when the prosthetic heart valve is to be replaced by another prosthetic heart valve because of clot formation, calcification, or other interference with the movement of the valve disc 12.

Figs. 2, and also Figs. 4a and 4b, more particularly illustrate the novel structure of the prosthetic heart valve 2 in order to permit only the valve ring 10 and its disc 12 to be replaced, whenever necessary, thereby obviating the need for removing the

mounting ring 4 and its sutures 8 when replacing a defective prosthetic heart valve by a new one.

Thus, the valve ring 10 is constructed like a wheel rim. It is of U-shaped section, having a pair of opposed flanges 10a, 10b interconnected by a bridge 10c and open at the outer face of the ring, as best seen in Fig. 4b. In addition, the mounting ring 4 includes a clamping member 20 for clamping the valve ring 10 to is. Clamping member 20 is in the form of a coiled spring having approximately 1.5 loops and is enclosed within the fabric mounting ring 4. The coiled-spring clamp is seated on the bridge portion 10c of the valve ring 10 between its flanges 10a, 10b, but may be unseated therefrom in order to permit replacement of valve ring 10 by another valve ring and valve member 12, while leaving the sutures 8, the mounting ring 4, and the coiled-spring clamp 20, in place in the annulus.

The use of a coiled spring 20 for the clamping member provides an additional advantage in that the coiled spring, being expansible in diameter, can accomodate valve rings of different diameters, for example when a prosthetic heart valve has been used to replace a natural, defective valve in a growing child but has to be replaced because of the growth in the heart size of the child.

Fig. 3 illustrates an instrument that may be used for inserting for removing the valve ring 10 and its valve member 12 from the sutured mounting ring 4 and coiled-spring clamp 20 whenever it may be required to replace the valve. Figs 4a, 4b illustrate the manner of using the instrument of Fig. 3 for removing the valve ring and valve member. Figs. 5a, 5b illustrate a modification in the instrument of Fig. 3 and the manner of using it for reapplying another

valve ring and valve member in the place of the removed one.

The instrument illustrated in Fig. 3, therein generally designated 30, comprises a pair of handles 32, 34. Handle 32 is relatively fixed, and handle 34 is pivotably mounted by pin 36 to it. A leaf spring 38 interposed between the two handles 32, 34 urges them apart, so that a light squeezing pressure will pivot handle 34 towards handle 32 against the action of spring 38.

Instrument 30 illustrated in Fig. 3 further includes a rod 40 fixed at one end to an extension 41 of the fixed handle 42. Rod 40 terminates at its opposite end in an upstanding abutment 42 which serve as one jaw of the instrument. The movable handle 34 is formed with a lever arm extension 44 on the opposite side of pivot pin 36, which extension is coupled by a link 46 to a slide 48 slidably receivable on rod 40. The opposite end of slide 48 carries a second jaw 50 formed with an inner face 51 aligned with the top face of jaw 42, and with a tapered surface 52 at its outer tip.

It will be seen that jaw 50 is movable along a rectilinear path, parallel to the axis of rod 40, when handle 34 is pivoted towards handle 32 by the application of a squeezing pressure. Jaw 50 is located so that, when the two handles are squeezed together, the inner face 51 of jaw 50 just clears the top face of jaw 42 and moves slightly past it as shown in Fig. 4b. During this movement, tapered surface 52 serves as a cam surface which, as illustrated in Figs. 4a and 4b, unseats coiled-spring clamp 20 from the rim of ring 10 and thereby permits the ring, together with the valve disc 12, to be removed from the mounting ring 4.

The foregoing operations for removing valve ring 10 and its valve disc 12 from the mounting ring 4, without disturbing sutures 8 fixing the mounting ring in place, are particularly seen in Figs. 4a and 4b. Thus, whenever a defective valve is to be replaced, the two jaws 42, 50 of the instrument 30 illustrated in Fig. 3 are applied to valve ring 10 of the defective valve, with the tapered tip 52 of jaw 50 aligned with the coiled-spring clamp 20 on the outer side of the valve ring 10, and the inner face of jaw 42 abutting against the inner side of valve ring 10. This is the position illustrated in Fig. 4a.

The physician then squeeze handle 34 towards handle 32. This causes jaw 50 to move along a rectilinear path parallel to the axis of rod 40, to bring the tapered tip 52 of jaw 50 into engagement with the coiled-spring clamp 20 at its line of contact with valve ring 10. A further squeezing of the two handles 32, 34 moves jaw 50 towards jaw 42, causing the tapered surface 52 of jaw 50 to cam upwardly the coiled-spring clamp 20 until it unseats from valve ring 10.

The latter position is illustrated in Fig. 4b, wherein it will be seen that tapered surface 52 of jaw 50 has unseated coiled-spring clamp 20 from valve ring 10, and at the same time the valve ring is tightly clamped between two jaws 42, 50 so that the valve ring can be removed by the same instrument 30 while the coiled-spring clamp is retained in place in the heart annulus.

Fig. 5a and 5b illustrate the manner of using instrument Fig. 3, with a slightly modification in the structure of the two jaws, therein designated 42', 50', also for reattaching another valve ring, therein designated 10', containing another valve member to the mounting ring 4 already sutured in

place. Actually, it is only necessary to modify jaw 50' such that its inner face 51', instead of being aligned with the top face 42' of jaw 42 as in Figs. 3, 4a, 4b, rather depends below it such as to abut against the end of the new valve ring 10', as shown in Fig. 5a.

In attaching a new valve ring 10' to the sutured mounting ring 4, the new valve ring 10' is placed between jaws 50' and 42' of the instrument. The lower end of the new ring 10' is then placed to engage the coiled-spring clamp 20 of the mounting ring 4, with the upper end of the valve ring 10' spaced slightly forwardly of clamp 20, and with the inner face of abutment 42' engaging the inner face of the mounting ring containing clamp 20. This is the position illustrated in Fig. 5a.

Then, as shown in Fig. 5b, the handles of the instrument are squeezed towards each other to move jaw 50' towards jaw 42' causing the upper end of valve ring 10' to move towards the coiled-spring clamp 20 until the valve ring snaps into place within the coiled spring, as shown in Fig. 5b.

During this insertion step, it may be necessary or desirable to include an additonal clamp, shown at 60 in Figs. 5a and 5b, for securely holding the lower part of valve ring 10' seated in the coiled spring clamp 20 during the insertion of the upper part of the valve ring in the manner described above.

The instrument illustrated in Fig. 6 may also be used for attaching a new valve ring, therein designated 110, and valve member (not shown) to a previously sutured mounting ring 104 containing a coiled-spring clamp 120. Thus, movable jaw 150 includes a lip 151 for more securely holding the valve ring 110, and the fixed jaw 142 similarly includes a lip 143 for more securely holding the clamp 120 when

the valve ring is moved to become seated within the clamp. The lower end of the valve ring 110 is retained within the lower end of the clamp 120 by a wrench type clamp 160 including a fixed jaw 162 and a movable jaw 163 movable by rotating nut 164 on handle 165.

While the invention has been described with respect to one preferred embodiment as applied to a disc-type prosthetic valve, it will be appreciated that the invention may be used with other types of prosthetic valves. Many other variations, modifications and applications of the invention will be apparent.

WHAT IS CLAIMED IS:

1. A prosthetic heart valve, comprising a mounting ring of suturable material for mounting the valve in an annulus in the heart by the use of sutures, a valve ring carried by said mounting ring, and a movable valve member carried by said valve ring; characterized in that said mounting ring includes a clamping member clamping said valve ring thereto, which clamping member is openable to release said valve ring and valve member, and to permit replacement of the valve ring and its valve member by another valve ring and valve member while leaving the mounting ring and its sutures in place in said annulus.

2. The prosthetic heart valve according to Claim 1, wherein said clamping member is in the form of a ring having a diameter which is expansible in order to accomodate valve rings of different diameters.

3. The prosthetic heart valve according to either of Claims 1 or 2, wherein said clamping member is a coiled spring of annular shape.

4. The prosthetic heart valve according to Claim 3, wherein said coiled spring has approximately 1.5 loops.

5. The prosthetic heart valve according to either of Claims 3 or 4, wherein said valve ring includes a rim of U-shaped section for receiving said coiled-spring clamping member.

6. The prosthetic heart valve according to any one of Claims 3-5, wherein said suturable mounting ring is of fabric.

7. An instrument for use in removing a valve member and its valve ring from a clamping ring included within a mounting ring sutured in an annulus

in the heart, and/or in inserting another valve member and valve ring in its place, comprising:

a first handle;

a second handle pivotably mounted to the first handle and grippable therewith by the user's hand so as to be movable towards and away from the first handle by a hand-squeezing pressure;

a fixed jaw fixed at one end to said first handle and having an abutment at its opposite end;

and a movable jaw coupled to said second handle by a coupling effective to cause said movable jaw to move towards and away from said abutment along a rectilinear path parallel to the axis of said fixed jaw when the second handle is pivoted towards and away from said first handle.

8. The instrument according to Claim 7, wherein the instrument is used for removing the valve member and its valve ring from the mounting ring, the outer tip of said movable jaw including a tapered surface effective to unseat the clamping ring from the valve ring when the movable jaw is moved towards said fixed jaw.

9. The instrument according to Claim 7, wherein the instrument is used for attaching a new valve member and its valve ring to the mounting ring, the outer tip of said movable jaw including an abutment depending below the upper surface of said abutment of the fixed jaw so that the two abutments engage the valve ring and the clamping ring therebetween, and movement of the movable jaw causes the valve ring to seat in the clamping ring.

10. The instrument according to any one of Claims 7-9, wherein said movable jaw is slidably mounted on said fixed jaw and is coupled to said second handle by a link pivotably mounted at one end

to an extension of said second handle and at the opposite end to said movable jaw.

11. A prosthetic heart valve substantially as described with reference to and as illustrated in the accompanying drawings.

12. An instrument for use in removing a valve member and its valve ring from a mounting ring sutured in an annulus in the heart, and/or inserting another valve member and valve ring in its place, substantially as described with reference to and as illustrated in the accompanying drawings.

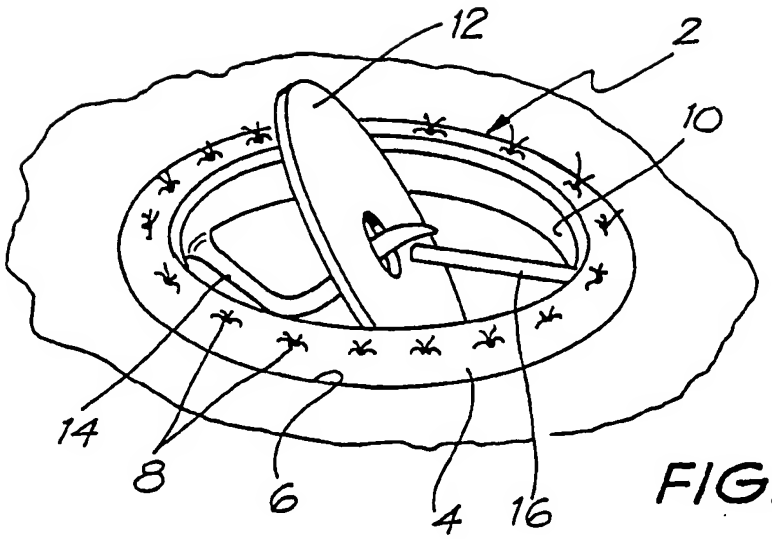

FIG. 1

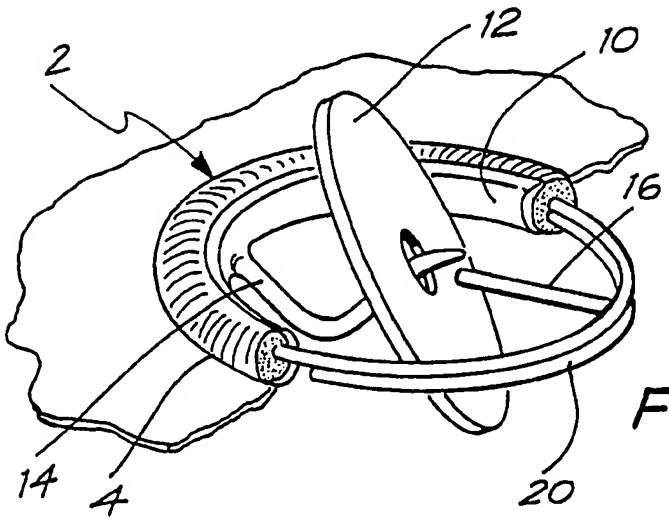

FIG. 2

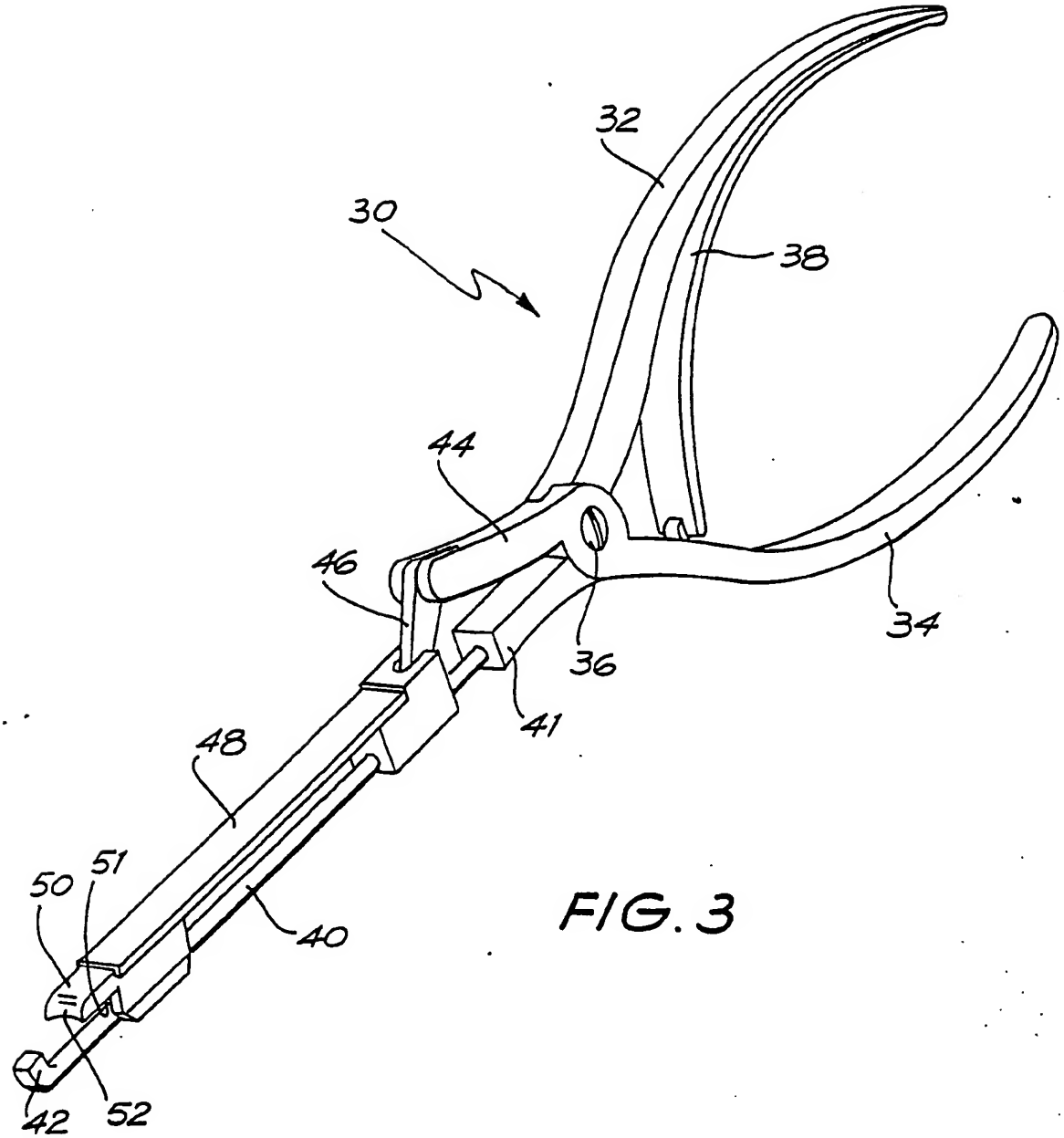

FIG. 3

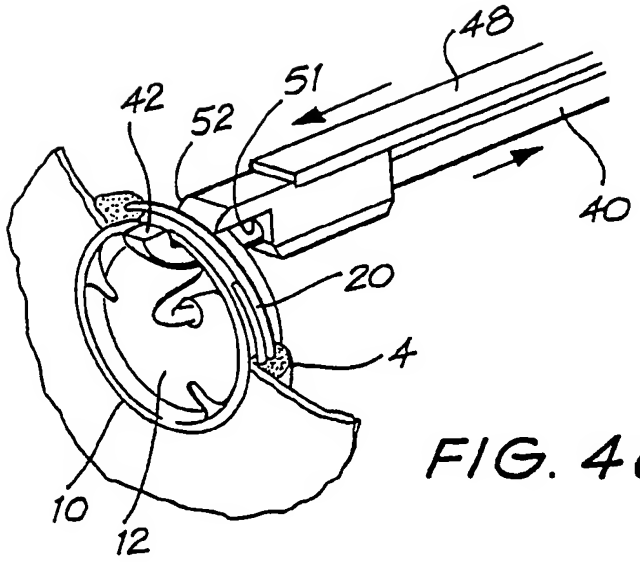

FIG. 4a

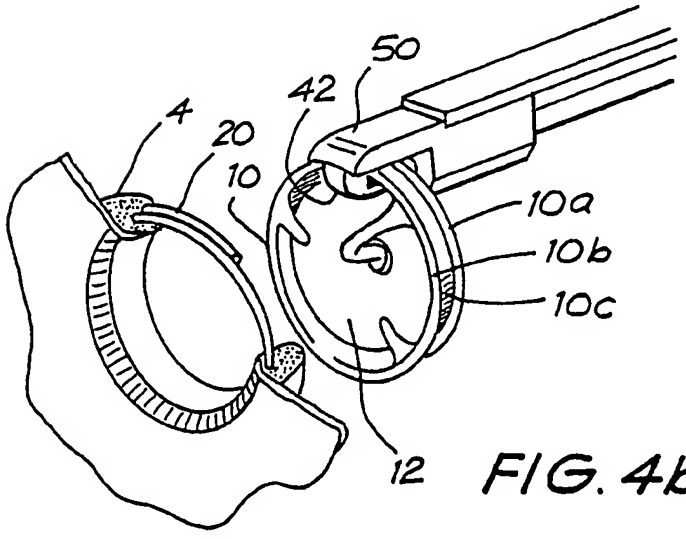

FIG. 4b

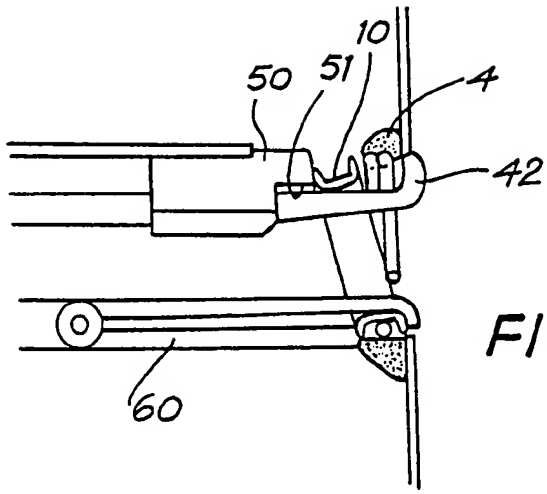

FIG. 5a

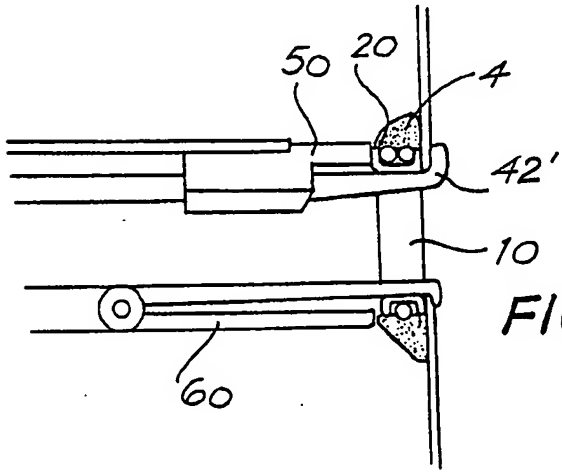

FIG. 5b

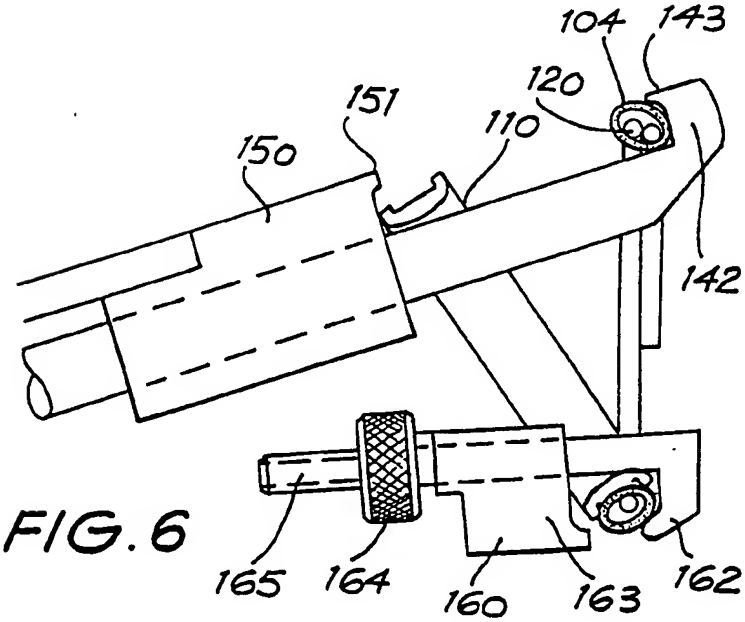

FIG. 6

INTERNATIONAL SEARCH REPORT

International Application No PCT/AU 87/00075

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl.[4] A61F 2/24, 2/76, A61B 17/50, 17/28

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC	A61F 2/24, 1/22

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

AU : IPC as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	GB,A, 1093599 (SEIDEL) 6 December 1967 (06.12.67)	(1)
Y	US,A, 4197593 (KASTER et al) 15 April 1980 (15.04.80)	(1-6,11)
Y	US,A, 3579642 (HEFFERNAN) 25 May 1971 (25.05.71)	(1-6,11)
A	US,A, 3996623 (KASTER) 14 December 1976 (14.12.76)	(1-6,11)
A	US,A, 3099016 (EDWARDS) 30 July 1963 (30.07.63)	(1-6,11)
A	AU,B, 23104/84 (557515) (HEMEX, INC.) 19 July 1984 (19.07.84)	(1-6,11)

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
12 June 1987 (12.06.87)	(20.06.87) 20 JUNE 1987
International Searching Authority	**Signature of Authorized Officer**
Australian Patent Office	A. HENDRICKSON

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This International search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers .. .. because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim numbers ..... because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claim numbers ..... because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

- claims 1-6,11, a prosthetic heart valve.
- claims 7-10,12, an instrument for use in removing a valve ring from a clamping ring.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers: 1-6,11

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON
INTERNATIONAL APPLICATION NO. PCT/AU 87/00075

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Members					
US 4197593	DE	290822	FR	2437201		
AU 23104/84	BR	8400148	CA	1211254	DK	175/84
	EP	119357	ES	528890	JP	59137051
	NO	834641	US	4535483		

END OF ANNEX